APR 1 8 2001

K010853

Section 2 - 510 (k) Summary of Safety and Effectiveness

a. Summary of Safety and Effectiveness

Contact Person

Roxane K. Baxter
Manager of Regulatory Affairs
Boston Scientific / Target
47900 Bayside Parkway
Fremont, CA 94538

Trade Name

Guider™ Softip™ Guiding Catheter XF 5F

Common Name

Guiding Catheter

Classification Name

Catheter, Percutaneous (21 CFR Section 870.1250)

Predicate Devices

Number	Description	Predicate for	Clearance Date
K962362	Cordis ENVOY® Guiding Catheter 5F	*Guider™ Softip™* Guiding Catheter XF 5F	8 August 1996
K961999	SCHNEIDER GUIDER *Softip®* Guiding Catheter 6F	*Guider™ Softip™* Guiding Catheter XF 5F	19 November 1996
K980453	SCHNEIDER GUIDER *Softip®* Guiding Catheter XF 6F	*Guider™ Softip™* Guiding Catheter XF 5F	11 August 1998

Intended Use

The *Guider Softip* Guiding Catheter XF 5F is designed for the introduction of interventional devices.

The *Guider Softip* Guiding Catheter XF 5F **Indications for Use** are as follows:

> *Guider Softip* Guiding Catheters are intended to facilitate the placement of interventional devices into the peripheral and coronary systems and, in addition for the XF models, into the neurovascular system.

Device Description

The *Guider Softip* Guiding Catheter XF 5F is a vascular access catheter that creates a stable conduit through which interventional devices can pass.

The subject device is constructed with a polymer liner on the inside diameter for lubricity, stainless steel wire reinforcement within the wall for torque transmission and strength, and polymer materials along the length of the catheter for support and flexibility. The catheter has an atraumatic tip and a hub/strain relief combination for kink resistance (at the hub), device connectivity, and device handling.

The *Guider Softip* Guiding Catheter XF 5F will be manufactured in multiple distal shape configurations and lengths. Engineering drawings of the catheter and diagrams of the distal shape configurations are provided in **Section 4.** Copies of the draft package label and Instructions for Use (package insert) for the *Guider Softip* Guiding Catheter XF 5F are provided in **Appendix 1.**

The *Guider Softip* Guiding Catheter XF 5F will be manufactured in the same facility and with similar procedures as the *Guider Softip* Guiding Catheter XF 6 – 9F models. The catheter consists of five (5) major components:

- Hub and strain relief
- Inner liner
- Reinforcement layer
- Outer layer
- Soft tip

Technological Characteristics

No new technological characteristics have been incorporated into the current design of the *Guider Softip* Guiding Catheter XF product line to create the *Guider Softip* Guiding Catheter XF 5F.

Product Feature Comparison

Feature	Cordis ENVOY® Guiding Catheter 5F Predicate cleared under K962362	*Guider™ Softip™* Guiding Catheter XF 5F Subject Device	SCHNEIDER GUIDER *Softip®* Guiding Catheter XF 6F Predicate cleared under K980453 & K961999
Intended Use	The ENVOY Guiding Catheter is intended for use in the peripheral, coronary and neurovasculature for the intravascular introduction of interventional / diagnostic devices.	*Guider Softip* Guiding Catheters are intended to facilitate the placement of interventional devices into the peripheral and coronary systems and, in addition for the *XF* models, into the neurovascular system.	*Guider Softip* Guiding Catheters are intended to facilitate the placement of interventional devices into the peripheral and coronary systems and, in addition for the *XF* models, into the neurovascular system.
Design:			
Size (French)	5 French	5 French	6 French
Inside diameter (ID)	0.050"	0.053"	0.064"
Outside diameter (OD)	0.065"	0.067"	0.078"
Materials [1]	Predominantly PTFE and nylons [2]	Predominantly polymer, stainless steel, and polycarbonate	Predominantly polymer, stainless steel, and polycarbonate

1 Equivalency in materials is demonstrated by *in vitro* performance test results (summarized in **Section 5**) and biocompatibility test results (summarized in **Section 6**).

2 Materials in the Cordis predicate device are not known with certainty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Roxane K. Baxter
Manager of Regulatory Affairs
Boston Scientific / Target
47900 Bayside Parkway
Fremont, CA 94538

Re: K010853
Trade Name: *Guider™ Softip™* Guiding Catheter XF 5F
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: April 5, 2001
Received: April 6, 2001

Dear Ms. Baxter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Boston Scientific
TARGET

INDICATIONS FOR USE STATEMENT

510(k) Number: K010853

Device Name: *Guider™ Softip™* Guiding Catheter XF 5F

Indications for Use:

Guider Softip Guiding Catheters are intended to facilitate the placement of interventional devices into the peripheral and coronary systems and, in addition for the *XF* models, into the neurovascular system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010853